CERTIFICATE: IN-VITRO TESTING WITH RADIOACTIVE MATERIAL UNDER GENERAL LICENSE

North Dakota Department of Health
Radiation Control Program
SFN 8423 2/06

Section 33-10-03-04.2.f of the North Dakota Radiological Health Rules herewith establishes a general license authorizing physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, and hospital to possess certain small quantities of radioactive material for in-vitro clinical or laboratory tests not involving the internal or external administration of the radioactive material or the radiation therefrom to human beings or animals. Possession of radioactive material under this section is not authorized until the physician, veterinarian, clinical laboratory, or hospital has filed this form and received from the Department a validated copy of this form with certification number.

Submit form to: North Dakota Department of Health, Division of Air Quality, 2nd Floor, 918 East Divide Ave., Bismarck, ND 58501-1947. Phone: 701-328-5188 Fax: 701-328-5185
A certification number will be assigned and a validated copy of this form will be returned. This certificate is valid for 3 years from the date of issue.

INSTRUCTIONS

Please print or type below, the name and address (including zip code) of the physician, clinical laboratory, or hospital for whom or for which this form is filed.

<table>
<tr><td colspan="2">Name</td><td colspan="2">Address</td></tr>
<tr><td colspan="2">City</td><td>State</td><td>Zip Code</td></tr>
<tr><td colspan="2">I hereby apply for a certification for use of radioactive material for (check one)</td><td colspan="2">Certification Number</td></tr>
<tr><td></td><td>Myself, a duly licensed physician (authorized to dispense drugs) in the practice of medicine</td><td colspan="2">Expires</td></tr>
<tr><td></td><td>Myself, a veterinarian in the practice of veterinary medicine</td><td colspan="2" rowspan="3">Certificate Validated By
(For Department use only, do not write in this space)</td></tr>
<tr><td></td><td>The above-named clinical laboratory</td></tr>
<tr><td></td><td>The above-named hospital</td></tr>
<tr><td colspan="4">If place of use is different from address listed above, please give complete address:</td></tr>
</table>

CERTIFICATION

1. All information in this certification is true and complete.

2. Appropriate radiation measuring instruments are available to carry out the tests for which radioactive material will be used under the general license for in-vitro testing. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive material.

3. I understand that the Department requires that any change in the information furnished on this certificate be reported to the Department within 30 days from the effective date of such change.

4. I have read and understand the provisions of the General License for In-Vitro Clinical or Laboratory Testing; and I understand that compliance with those provisions is required for all radioactive material received, acquired, possessed, used, or transferred under the general license for which this Certificate is filed with the North Dakota Department of Health.

Signature of Person Filing Form **Date**

Printed Name **Title**

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 33-10-03-04.2.

f. General license for use of radioactive material for certain in vitro clinical or laboratory testing. (The new drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.)

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs 2, 3, 4, 5, and 6, the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(a) Carbon-14, in units not exceeding three hundred seventy kilobecquerels [10 microcuries] each.
(b) Cobalt-57, in units not exceeding three hundred seventy kilobecquerels [10 microcuries] each.
(c) Hydrogen-3 (tritium), in units not exceeding one and eighty-five hundredths megabecquerels [50 microcuries] each.
(d) Iodine-125, in units not exceeding three hundred seventy kilobecquerels [10 microcuries] each.
(e) Mock iodine-125 reference or calibration sources, in units not exceeding one hundred eighty-five becquerels [0.005 microcurie] of iodine-129 and one hundred eighty-five becquerels [0.005 microcurie] of americium-241 each.
(f) Iodine-131, in units not exceeding three hundred seventy kilobecquerels [10 microcuries] each.
(g) Iron-59, in units not exceeding seven hundred forty kilobecquerels [20 microcuries] each.
(h) Selenium-75, in units not exceeding three hundred seventy kilobecquerels [10 microcuries] each.

(2) No person shall receive, acquire, possess, use, or transfer radioactive material pursuant to the general license established by paragraph 1 until the person has filed Department Form SFN 8423, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the department and received from the department a validated copy of Department Form SFN 8423 with certification number assigned. The physician, veterinarian, clinical laboratory, or hospital shall furnish on Department Form SFN 8423 the following information and such other information as may be required by that form:

(a) Name and address of the physician, veterinarian, clinical laboratory, or hospital.
(b) The location of use.
(c) A statement that the physician, veterinarian, clinical laboratory, or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in paragraph 1 and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by paragraph 1 shall comply with the following:

(a) The general licensee shall not possess at any one time, pursuant to the general license in paragraph 1, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, or cobalt-57 in excess of seven and four-tenths megabecquerels [200 microcuries].
(b) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
(c) The general licensee shall use the radioactive material only for the uses authorized by paragraph 1.
(d) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, the United States nuclear regulatory commission, any agreement state, or a licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
(e) The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in subparagraph e of paragraph 1 as required by subsection 1 of section 33-10-04.1-14.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to paragraph 1:

(a) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the United States nuclear regulatory commission, any agreement state, or a licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or mock iodine-125 to persons generally licensed under this subdivision or its equivalent; and
(b) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

[1] This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to this article and a general license of the United States nuclear regulatory commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

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Name of manufacturer

[2] This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to this article and a general license of a licensing state.

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Name of manufacturer

(5) The physician, veterinarian, clinical laboratory, or hospital possessing or using radioactive material under the general license of paragraph 1 shall report, in writing, to the department, any changes in the information furnished by the physician, veterinarian, clinical laboratory, or hospital in the "Certificate - In Vitro Testing with Radioactive Material Under General License", Department Form SFN 8423. The report shall be furnished within thirty days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of paragraph 1 is exempt from the requirements of chapters 33-10-04.1 and 33-10-10 with respect to radioactive material covered by that general license. However, persons using mock iodine-125 reference or calibration sources described in subparagraph e of paragraph 1 shall comply with the provisions of subsection 1 of section 33-10-04.1-14 and subsections 1, 2, 3, and 5 of section 33-10-04.1-16.